June 26, 2003

• What kinds of new products will manufacturers develop because of claims or a footnote or disclosure statement?

• What kinds of products will manufacturers stop producing because of claims or a footnote or disclosure statement?

• What First Amendment issues, if any, would be raised by establishing qualifying criteria for *trans* fat in *trans* fat claims and other nutrient content or health claims with existing criteria for saturated fat and by requiring a footnote or disclosure statement?

• How will manufacturers weigh the consumer concerns about both saturated and *trans* fats with the functional properties of those fats in the food. For example, if, as some manufacturers have claimed, functional considerations may sometimes cause *trans* fat to be replaced with equal or greater amounts of saturated fat, then how will consumers react to such an inappropriate substitution where a product ~~that will~~ list fewer grams of *trans* fat, but ~~will~~ list more grams of saturated fat and report a higher % DV for saturated fat? At what ratio of substitution of saturated fat for *trans* fat would it not be advantageous to a manufacturer to make such a substitution, even with a claim or footnote or disclosure statement? What steps could FDA take to discourage such unhealthful reformulation and encourage healthful reformulation?

• In order to comply with the Small Business Regulatory Enforcement Fairness Act of 1996, what options for regulatory relief should we consider giving to small businesses?

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal government holidays. FDA

has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids," National Academy Press, Washington, DC, pp. S1–S17, 8–1 to 8–97, and 11–1 to 11–48, 2002 (Internet address: *http://www.nap.edu/books/0309085373/html/*).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans*, 5th ed., Washington DC; Home and Garden Bulletin No. 232, 2000 (Internet address: *http://www.health.gov*).

3. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), chapter II, "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," 2001, (Internet address: *http://www.NHLBI.nih.gov/guidelines/cholesterol/index.htm*).

VW FDA
ADD REFERENCES 4+5

IV. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.